MAY 17 2000

K001348 p.1/2

**11.0 510(k) Summary**

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. The submitter of this premarket notification is:

Dave Osborn
Regulatory Affairs Engineer
Healthcare Solutions Group
Agilent Technologies
3000 Minuteman Road
Andover, MA 01810-1085

Tel: 978 659 3178
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This summary was prepared on 27 April, 2000

2. The name of this device is the Agilent Technologies ST/AR ST and Arrhythmia Software, Release C.0. Classification names are as follows:

| Classification | ProCode | Description |
|---|---|---|
| 870.1025, III | 74 MLD | Monitor, ST Alarm |
| 870.1025, III | 74 DSI | Arrhythmia Detector and Alarm |
| None | 74 MHX | Physiological Monitor, Patient Monitor |

3. The new device is substantially equivalent to the previously cleared ST/AR ST and Arrhythmia Software device marketed pursuant to K964122 and K991773, as well as Viridia CMS and 24/26 Rev K with EASI ST, K992595 and the 78534C option A03, ST Segment Monitoring, K870380.

4. The modification is a software-based change that provides ST analysis and alarms on derived 12-Lead ECG from EASI lead placements.

5. The new device has the same Indications for Use as the legally marketed predicate device. Where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

6. The new device has the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that ST/AR with EASI-ST software functionality meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2000

Mr. Dave Osborn
Regulatory Affairs Engineer
Agilent Technologies, Inc.
Healthcare Solutions Group
3000 Minuteman Road
Andover, MA 01810-1099

Re: K001348
Agilent Technologies ST/AR ST and Arrhythmia Software Release C.0
Regulatory Class: III (three)
Product Code: MHX
Dated: April 27, 2000
Received: April 28, 2000

Dear Mr. Osborn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sierely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001348

Device Name: Agilent Technologies ST/AR Software, Release C.0.

Indications for Use: Where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

The intended use of the ST/AR ST analysis algorithm is to monitor an adult patient's ECG for ST segment elevation or depression and produce events/alarms for all possible ECG leads. The ST analysis algorithm is capable of monitoring paced and non-paced adult patients.

Note: The ST algorithm does not analyze ventricularly paced or ventricular ectopic beats.

for Mark N. Milhorn

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001348

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** **OR** **Over-The-Counter Use**
**(Per 21 CFR 801.109)**
(Optional Format 1-2-96)